

REMARKS

Upon entry of this amendment, Claims 1-15 and 32-47 will be pending. Claim 16-23 have been canceled without prejudice or disclaimer. Claims 32-47 have been added. Support for the new claims is found, for example, in original Claims 1-16, and paragraphs 26-32 and 35 of the present specification. In addition, the added claims include the compounds in columns 3-4 of US Patent No. 5,462,946, which have been added in accordance with MPEP §2163.07(b).

The specification has been amended to correct a typographical error.

The rejections of Claims 16-23 under 35 USC §§ 101, and 112, second paragraph, have been rendered moot by the deletion of these claims. To the extent that the rejections under 35 USC §§ 112, first paragraph, and 102 apply to Claims 16-31, these rejections also have been rendered moot by the deletion of these claims.

Applicants traverse the rejection of Claims 1-23 on the ground of nonstatutory obviousness-type double patenting over Claims 16-25 of US Application No. 10/675,225. The Office stated that present Claims 1-23 “are construed to read on any method of treatment employing the administering of the instant claimed nitroxide compounds as the term ‘preventing’ or ‘prophylactic’ are construed to mean the absolute absence of ischemia.” Applicants respectfully submit that according to MPEP § 2111, “pending claims must be ‘given their broadest reasonable interpretation consistent with the specification,’” quoting Phillips. MPEP § 2111 also states that the PTO “determines the scope of claims in patent applications not solely on the basis of claim language, but upon giving claims their broadest reasonable construction ‘in light of the specification as it would be interpreted by one of ordinary skill in the art.’”

Applicants respectfully submit that the Office’s construction that the pending claims read on “any method of treatment” does not comport with the language of the claims or the present specification. Specifically, independent Claims 1 and 9 include a step of either identifying a human patient that is susceptible to ischemia or identifying a patient scheduled to undergo a medical procedure involving a significant risk of ischemia, respectively. In addition, as nonlimiting examples, paragraphs 11-14 of the present specification describe how a patient may be identified as susceptible to ischemia by using various diagnostics or assessing risk factors. As the claims include an explicit identifying step and the specification does not suggest that the claims should be read on “any method of treatment,” Applicants respectfully submit that the

Office has not properly construed the claims. Thus, Applicants respectfully submit that the Office has not established that a method comprising the claimed identifying step is obvious over Claims 16-25 of the '225 Application, which is directed in part to "topically applying a sufficient amount of nitroxide radioprotector to prevent or treat harmful side effects caused by radiotherapy."

Further, Applicants respectfully submit that the presently pending claims should not be construed to read on the "absolute absence of ischemia" as this construction is inconsistent with the specification. Applicants respectfully submit that with respect to the word "prevent," the specification states in paragraph 35 that "the term 'prevent' generally relates to *reducing the risk of ischemia* occurring, completely preventing ischemia from occurring, and/or preventing the negative effects of ischemia, including stroke (emphasis added)." Thus, the Office's construction of the "absolute absence of ischemia" is inconsistent with the specification.

If the claims are properly construed, the '225 Application would not anticipate the claimed methods. Thus, Applicants respectfully request withdrawal of this rejection.

Applicants traverse the rejection of claims 1-23 under 35 USC § 112, first paragraph (enablement). Applicants gratefully acknowledge the Examiner's indication that the specification is enabling for methods of reducing the harmful effects of ischemia comprising administering certain nitroxide compounds such as Tempol. Claims 2 and 10 recite 4-hydroxy-2,2,6,6-tetramethylpiperidine-1-oxyl, thus it is not clear why these claims have been rejected.

The Office alleges with respect to the breadth that Claim 1's step of "identifying a human patient that is susceptible to ischemia" includes "any and all living humans," apparently without consideration whether the patient is susceptible to ischemia as recited in the claim. Further, the Office construed the phrase "a sufficient amount of nitroxide to prevent a harmful effect of ischemia in the human patient prior to the onset of ischemia" to mean "the absolute absence of ischemia." As a discussed above, the Applicants respectfully submit that the Office's construction is not consistent with the specification and/or the claims, and thus the Office has not given the "broadest reasonable construction" to these terms.

In addition, the Office construed Claim 1 to encompass "administering any and all nitroxide to a patient identified as being susceptible to ischemia." Applicants respectfully submit that according to the specification in paragraph 24 "nitroxide ... generally refers to stable free

radical compounds that are capable of reacting with a variety of biologically relevant compounds such as free radicals...." Further, Applicants have specifically exemplified nitroxides in paragraphs 27-33 of the present Application. Of course, "[t]he presence of inoperative embodiments within the scope the claim does not necessarily render a claim nonenabled." Please see the PTO's "Training Materials for Examining Patent Applications with Respect to 35 U.S.C. Section 112, First Paragraph-Enablement Chemical/Biotechnical Applications" (hereinafter "Training Materials"). In addition, the Training Materials state that "a considerable amount of experimentation is permissible if it is merely routine...." The Applicants have stated that nitroxides have a particular activity, and respectfully submit that such activity may be determined using routine assays.

Thus, Applicants respectfully submit that the claims are enabled in light of the present specification.

Applicants have added Claims 34-47 directed in part to the subject matter acknowledged by the Office to be enabled, and thus Applicants submit that this rejection would not apply to these newly added claims.

Applicants traverse the rejection of claims 1-23 under 35 USC § 102(b) as being anticipated by Mitchell *et al.* (US patent 5,462,946, hereinafter "Mitchell"). The Office states that "the term '[a] method of treatment comprising identifying a human patient that is susceptible to ischemia' as recited in claim 1, and the term 'identifying a patient scheduled to undergo a medical procedure involving a significant risk of ischemia as recited in claim 9 are construed to be inherent characteristics of the claimed method."

According to MPEP § 2112, "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" Applicants respectfully submit that the Office has not established that "identifying a human patient that is susceptible to ischemia" or "identifying a patient scheduled to undergo a medical procedure involving a significant risk of ischemia" is necessarily present in Mitchell, which is directed to "treating the effects of oxidative stress." Further, the Office has not established that the identifying step is not based on

probabilities or possibilities. Applicants respectfully submit that the identifying steps in the present claims are not inherent features of the claimed method. Moreover, as discussed above, Applicants respectfully submit that the Office has not properly construed the claims in light of the specification.

Further, with respect to Claim 1, the Office has not established that Mitchell discloses administering to a patient "prior to the onset of ischemia" according to Claim 1, or "prior to the medical procedure" according to Claim 9. Furthermore, Mitchell does not disclose the human patient's susceptibility to ischemia that arises from a medical procedure associated with a significant ischemic risk (Claim 3), wherein the medical procedure is treatment of a hemorrhage (Claims 4 and in 11), an aneurysm (Claims 5 and 12), surgery (Claims 6 and 13), or an endovascular procedure (Claims 7 and 14).

Moreover, as discussed above, Applicants respectfully submit that the Office has not properly construed the claims.

Thus, Applicants respectfully submit that the Office has not established that Mitchell anticipates the present claims. Withdrawal of this rejection, therefore, is respectfully requested.

In addition, Applicants respectfully submit that Mitchell teaches away from administering nitroxide prior to the onset of ischemia or prior to a medical procedure. Specifically, Mitchell states, for example, in column 4, lines 43-44, column 5, lines 26-28 and Claim 12 therein, that the invention is directed to "a method for treating the effects of oxidative stress." Column 5, lines 31-35 and Claim 13 therein specifies the oxidative stress that is being treated. There is no disclosure relating to administering the nitroxide before the effects of oxidative stress are present, for example.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior

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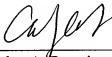
prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: 
Carolyn A. Favorito
Registration No. 39,183
Attorney of Record
Customer No. 20995
(949) 760-0404

5547067/dp
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